NOT FOR PUBLICATION

Civil No. 09-0946 (RBK/AMD) (Docket No. 6)
Civil No. 08-0854 (RBK/AMD) (Docket No. 23)
Civil No. 07-2863 (RBK/AMD) (Docket No. 32)
Civil No. 08-0855 (RBK/AMD) (Docket No. 26)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

WARREN and LISA HAGGERTY, both individually and on behalf of JOHN HAGGERTY, a minor,	:	
Plaintiffs,	:	Civil No. 09-946 (RBK/AMD)
v.	:	**OPINION**
NOVARTIS PHARMACEUTICALS CORPORATION, et al.,	:	
Defendants.	:	

MARGI MEHLOS, both individually and on behalf of TOBY MEHLOS, a minor,	:	
Plaintiffs,	:	Civil No. 08-854 (RBK/AMD)
v.	:	**OPINION**
NOVARTIS PHARMACEUTICALS CORPORATION, et al.,	:	
Defendants.	:	

KIMBERLY MAGUIRE, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, et al., Defendants.	:	Civil No. 07-2863 (RBK/AMD) **OPINION**

DANIEL MCGRAW, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, et al., Defendants.	:	Civil No. 08-855 (RBK/AMD) **OPINION**

KUGLER, United States District Judge:

This matter comes before the Court upon motions by Plaintiffs Warren Haggerty and Lisa Haggerty, both individually and on behalf of their son John Haggerty; Margi Mehlos, both individually and on behalf of her son, Toby Mehlos; Kimberly Maguire; and Daniel McGraw (collectively, "Plaintiffs") to remand their cases against Defendants Novartis Pharmaceuticals Corporation; Novartis Pharma, GMBH; Novartis, AG; Astellas Pharmaceuticals, USA, Inc.; and Astellas Pharmaceuticals, Inc. (collectively, "Defendants") to the New Jersey Superior Court where they were originally filed. Plaintiffs' Complaints allege violations of the New Jersey

Products Liability Act ("NJPLA"), N.J. Stat. Ann. § 2A:58C-1, et seq., the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1, et seq., and the New Jersey common law. Because the Court determines that it does not possess subject matter jurisdiction, Plaintiffs' cases will be remanded to New Jersey Superior Court.

I. BACKGROUND[1]

For purposes of the instant motion, the facts of this case are relatively simple and straightforward. Defendants are companies engaged in the business of developing, manufacturing, and distributing pharmaceutical products. In 2000, Defendant Astellas Pharma, Inc. received Food and Drug Administration ("FDA") approval for a drug known as Protopic. In 2001, Defendant Novartis, AG received FDA approval for a drug known as Elidel. Both drugs are topical immunosuppressants, work similarly in the body, and have similar side effects.

In the early years of this decade, Plaintiffs suffered from various dermatological conditions such as eczema and dermatitis. To treat their conditions, Plaintiffs' physicians prescribed either Elidel or Protopic. Several years later, Plaintiffs developed cancer.

Plaintiffs' Complaints alleges that, as early as 2001, Defendants were aware that use of Elidel and Protopic increased the risk of systemic malignancies in pediatric patients. For example, in 2003, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee held an open meeting to discuss how to approach long-term monitoring for malignancy occurrence among patients treated with Elidel and Protopic. The subcommittee noted that the pre-clinical and clinical studies of both drugs suggested that these drugs may increase the risk of malignancies in the pediatric population. The subcommittee concluded that Defendants should

[1] The facts in this section are drawn from allegations in Plaintiffs' Complaints.

provide a "Black Box" warning of the potential effects of Elidel and Protopic in children under two years of age. In 2005, the FDA's Pediatric Advisory Committee convened a meeting to discuss the potential malignancy risk from use of Elidel and Protopic. Finally, in March, 2005, the FDA required Defendants to include a Black Box warning on Elidel and Protopic.

Plaintiffs claim that Elidel and Protopic either caused their cancer or caused cancer in their minor children. Plaintiffs further claim that they would not have used Elidel or Protopic had Defendants properly warned Plaintiffs and their physicians about the associated malignancy risks of which Defendants were aware. Plaintiffs' Complaints, originally filed in state court, proceed on various state law tort and contract theories including: (1) failure to warn; (2) defective design; (3) breach of express warranty; (4) breach of implied warranty; and (5) consumer fraud.[2] Plaintiffs seek punitive damages under the NJPLA and common law. Defendants subsequently removed to federal court on the basis 28 U.S.C. § 1331 as interpreted by the Supreme Court in Grable & Sons Metal Prods., Inc. v. Darue Engineering & Mfg., 545 U.S. 308 (2005). Plaintiffs now move to remand.

II. STANDARD

Pursuant to 28 U.S.C. § 1441(a), a defendant may remove an action filed in state court to a federal court with original jurisdiction over the action. Once an action is removed, a plaintiff may challenge removal by moving to remand the case back to state court. To defeat a plaintiff's motion to remand, the defendant bears the burden of showing that the federal court has jurisdiction to hear the case. Abels v. State Farm Fire & Cas. Co., 770 F.2d 26, 29 (3d Cir. 1995)

[2] Plaintiffs' moving papers indicate that they will no longer pursue their consumer fraud claims.

(citing Pullman Co. v. Jenkins, 305 U.S. 534, 537 (1939)). Generally, where the decision to remand is a close one, district courts are encouraged to err on the side of remanding the case back to state court. See Abels, 770 F.2d at 29 ("Because lack of jurisdiction would make any decree in the case void and the continuation of the litigation in federal court futile, the removal statute should be strictly construed and all doubts should be resolved in favor of remand.").

III. DISCUSSION

Plaintiffs argue that this Court is without jurisdiction to adjudicate their claims because they do not arise under federal law within the meaning of 28 U.S.C. § 1331 ("Section 1331").

Pursuant to Section 1331, federal jurisdiction lies over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331 (2006). Courts determine whether an action arises under federal law by looking to the content of the plaintiff's "well-pleaded complaint". U.S. Express Lines, LTD v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002) (quoting Merrell Dow Pharm., Inc. v. Thompson, 478 U.S. 804, 808 (1986)). In the ordinary case, federal jurisdiction is triggered under Section 1331 by a plaintiff who pleads a cause of action created by federal law. Grable, 545 U.S. at 312. At the outer limits of Section 1331, however, are those cases where jurisdiction lies by virtue of the existence of a significant issue of federal law imbedded in an otherwise state law claim. Id. Imbedded state law claims arise under federal law where the state law claim (1) "necessarily raise[s] a stated federal issue, actually disputed and substantial"; that (2) "a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." Id. at 314. As the Supreme Court has subsequently explained, Grable represents "a special and small category" of federal jurisdiction. Empire Healthchoice Assur., Inc. v. McVeigh, 547 U.S. 677, 699 (2006).

Defendants' jurisdictional theory centers on Plaintiffs' claim for punitive damages under the NJPLA.[3] Generally speaking, the NJPLA precludes recovery of punitive damages against a pharmaceutical company on the basis of harm allegedly caused by drugs that have been subject to FDA pre-market approval. N.J. Stat. Ann. § 2A:58C-5(c). By way of exception, the NJPLA authorizes a punitive damage recovery in those cases where plaintiffs can show fraud-on-the-FDA, in other words, that "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question." Id. Defendants contend that the NJPLA's requirement that plaintiffs prove fraud-on-the-FDA as a prerequisite to punitive damages necessarily interjects a disputed and substantial federal issue into Plaintiffs' state law claims.

In 2005, the Supreme Court decided Grable, and in so doing, provided district courts with an example of a state law claim that is sufficient to confer federal jurisdiction. In Grable, the Internal Revenue Service ("IRS") served a notice of tax delinquency on a corporation by certified mail, seized real property belonging to the corporation, and sold it to another company. 545 U.S. at 310. Five years later, the corporation brought a quiet title action in Michigan state court against the subsequent purchaser on the theory that the subsequent purchaser's title was invalid because the IRS served the delinquency notice by way of certified mail, in contravention of Title 26 U.S.C. § 6335, which the corporation interpreted to require personal service. Id. The defendant removed to federal court on the basis of the imbedded federal notice question. Id.

---

[3] Defendants also contend that Plaintiffs' state law failure to warn claims confer federal question jurisdiction under Grable. The Court will not consider this contention, however, as Defendants do not argue the matter in their moving papers. But, see, Sullivan v. Novartis Pharm., Corp., 575 F. Supp. 2d 640, 650 (D.N.J. 2008) (rejecting argument that plaintiffs' failure to warn claims supported jurisdiction under 28 U.S.C. § 1331).

The Supreme Court granted certiorari to consider the question of whether plaintiff's state law quiet title action arose under federal law by virtue of the imbedded federal notice question. In holding that the plaintiff's claim arose under federal law, the Court emphasized the fact that the federal notice question was clearly "at the heart" of the plaintiff's claim. Id. at 320. Indeed, the question of proper notice was dispositive and "the only legal or factual issue contested in the case." Id. at 315. The Court further noted that the Government's strong interest in collecting delinquent taxes necessitated that the IRS know whether its delinquency notices were required to be served personally or by mail. Id. Finally, the Court reasoned that state quiet title actions turning on questions of federal law were rare enough to not seriously "threaten to affect the normal currents of litigation." Id. at 319.

At the outset, the Court notes that numerous courts in this District have considered Defendants' argument that Plaintiffs' punitive damages claims fit into the narrow Grable framework, and all have found Defendants' arguments wanting. See, e.g., Devine v. Novartis Pharm. Corp., No. 08-859, 2009 WL 3446404 (D.N.J. Oct. 19, 2009); Reilly v. Novartis Pharm. Corp., No. 07-4665, 2009 WL 3010540 (D.N.J. Sept. 18, 2009) (report and recommendation); D'Anna v. Novartis Pharm. Corp., Nos. 08-1119, 09-651, 08-4675, 08-5740, 2009 WL 1662174 (D.N.J. June 15, 2009) (mem.); Sullivan v. Novartis Pharm. Corp., 602 F. Supp. 2d 527 (D.N.J. 2009) (hereinafter "Sullivan II"); Sullivan v. Novartis Pharm. Corp., 575 F. Supp. 2d 640 (D.N.J. 2008) (hereinafter "Sullivan I"); Brown v. Organon Int'l Inc., Nos. 07-3092, 07-3456, 08-2021, 2008 WL 2833294 (D.N.J. Jul. 21, 2008); Fields v. Organon USA, Inc., No. 07-2923, 2007 WL 4365312 (D.N.J. Dec. 12, 2007); DeAngelo-Shuayto v. Organon USA, Inc., No. 07-2923, 2007 WL 4365311 (D.N.J. Dec. 12, 2007); Von Essen v. C.R. Bard, Inc., No. 06-4786, 2007 WL

2086483 (D.N.J. Jun. 18, 2007) (report and recommendation); see also In re Aredia and Zometa Prods. Liab. Litig., No. 3:06-MD-1760, 2007 WL 649266 (M.D. Tenn. Feb. 27, 2007).

The Court is persuaded by the sound reasoning of these cases and agrees that Plaintiffs' claims presently before the Court do not fit within the narrow category of cases exemplified by Grable. Unlike Grable, resolution of Plaintiffs' fraud-on-the-FDA allegations will not dispose this case. In fact, the issue of punitive damages will only be reached, as a matter of course, if and when Plaintiffs' establish substantive liability.[4] Even then, a successful showing of fraud-on-the-FDA does not guarantee a punitive recovery. Rather, Plaintiffs will still have to show, by clear and convincing evidence and in light of a variety of statutory factors, that Defendants' bad acts and omissions "were actuated by actual malice or accompanied by a wanton and willful disregard" for the safety of foreseeable plaintiffs. N.J. Stat. Ann. § 2A:15-5.12. See, e.g., Reilly, 2009 WL 3010540, at *5 (finding plaintiffs' fraud-on-the-FDA theory of punitive damages insufficiently substantial to confer federal jurisdiction); Devine, 2009 WL 3446404, at *4 (same). Indeed, an issue that represents one step in a multi-step, multi-factor analysis of the propriety of one subset of damages can hardly be said to constitute the heart of this case.

The nature of the federal issue at play in Plaintiffs' punitive damages claim also counsels against jurisdiction. In the post-Grable case of Empire Healthchoice Assurance, Inc. v. McVeigh, the Supreme Court clarified that "fact-bound and situation-specific" imbedded federal

[4] Defendants do not presently argue that Plaintiffs' punitive damages claim is preempted by federal law. Defendants may, however, choose to pursue this argument at some later point in this litigation. Although the Court expresses no opinion on the matter, if Defendants do argue preemption, they may of course prevail. See McDarby v. Merck & Co., Inc., 949 A.2d 223, 276 (N.J. Super. Ct. App. Div. 2008) (holding that N.J. Stat. Ann. § 2A:58C-5(c) is preempted by the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq.) Such a victory would render any inquiry into Plaintiffs' fraud-on-the-FDA claims moot.

questions generally do not warrant federalizing an otherwise state law case. 547 U.S. at 701. In this case, resolution of the imbedded federal question will require the court to query whether the Elidel and Protopic-specific disclosures made by Defendants to FDA at various points in the regulatory process satisfied federal requirements.[5] Such an inquiry is necessarily fact-centric. See Brown, 2008 WL 2833294, at *4 ("The 'fraud on the FDA' questions relevant to the availability of punitive damages under the NJPLA . . . do not depend on the construction or interpretation of federal law."); D'Anna, 2009 WL 1662174, at *3 (expressing doubt that the federal issue imbedded in plaintiffs' NJPLA punitive damages claim would "require a sophisticated inquiry into the meaning of FDA regulations"). As a consequence, resolution of Plaintiffs' NJPLA claim is unlikely to govern numerous fraud-on-the-FDA cases in the future. See Empire Healthchoice, 547 U.S. at 701 (low probability that imbedded federal issue will govern future cases cuts against jurisdiction).

Defendants nonetheless argue that the imbedded federal issue is substantial enough to confer jurisdiction. In support of this argument, Defendants rely primarily on the Supreme Court's decision in Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). In Buckman, the Supreme Court considered whether a plaintiff's state-law failure to warn claim predicated on a fraud-on-the-FDA theory was preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") as amended by the Medical Devices Amendments of 1976 ("MDA"). Buckman, 531 U.S. at 343. The plaintiffs in Buckman alleged injury as a result of the use of

[5] To address Plaintiffs' punitive damages claim, the Court will likely have to consider whether Defendants have complied with the statutory requirements for new drug approval, see, e.g., 21 U.S.C. § 355, as well as FDA regulations mandating certain post-approval disclosures, see, e.g., 21 C.F.R. §§ 314.80, 314.81.

unsafe orthopedic bone screws in their spines. Id. The plaintiffs sued a consulting agency retained by the screws' manufacturer to assist it in complying with the federal regulatory process on the theory that the consulting company made fraudulent representations to the FDA in order to obtain market approval. Id. These misrepresentations, argued the plaintiffs, caused the FDA to approve the injury-causing device; whereas, FDA would never have approved the devices had the defendants not provided FDA with bad information. Id.

The Supreme Court held that the plaintiffs' state law claims were preempted. At the outset, the Court observed that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Id. at 347. Noting that FDA has the burden of pursuing the oft-competing goals of ensuring medical device safety and bringing products to market with alacrity, the Court cautioned that allowing the tort regimes of the fifty individual states to determine what disclosures ought to be made would have desultory effects. Id. at 350. Specifically, the Court was concerned with the possibility that diverse state regulation would inundate FDA with a flood of unnecessary disclosures, greatly increase compliance costs, and ultimately slow delivery of reasonably safe and effective medical devices to market. Id. at 350-51. In sum, the Court felt that "this sort of litigation would exert an extraneous pull on the scheme established by Congress . . . ." Id. at 353.

Despite the Supreme Court's strong emphasis on the federal character of fraud-on-the-FDA claims, Buckman does not control this case. As many courts have observed, Buckman was a preemption case and did not address the question of whether the plaintiffs' fraud-on-the-FDA claims conferred jurisdiction by arising under federal law. See Sullivan II, 602 F. Supp. 2d at

535 (collecting cases). Indeed, efficiency concerns such as those expressed by the Buckman court have less relevance here where Defendants do not argue that federal law alone should govern. Although the precise definition of a "substantial" federal question is unclear, see Alliance for Children, Inc. v. City of Detroit Pub. Schs., 475 F. Supp. 2d 655, 670 (E.D. Mich. 2007), the Supreme Court has signaled that an insubstantial question is generally not made substantial out of the fear that allowing state law to use and interpret federal standards will imperil the order and stability of federal regulatory regimes. See Merrell Dow Pharm., Inc. v. Thompson, 478 U.S. 804, 815-16 (1986) (observing that petitioners making these types of arguments should instead be arguing preemption). Accordingly, Buckman does not affect the Court's conclusion that the fraud-on-the-FDA issue imbedded in Plaintiffs' NJPLA claims does not satisfy the first Grable prong.

The Court is also concerned that finding federal jurisdiction in this case would significantly alter the division of judicial labor between state and federal courts. The instant case is one of at least nineteen similar cases filed in the District of New Jersey. Recently, more than fifty-four cases were removed to federal court on the basis of the federal question imbedded in N.J. Stat. Ann. 2A:58C-5(c). See, e.g., Brown, 2008 WL 2833294, at *4 (listing cases). Moreover, New Jersey is not the only state that has incorporated a showing of fraud-on-the-FDA into its punitive damage analysis. See, e.g., Ohio Rev. Code Ann. § 2307.80(C)(2) (West 2009); Or. Rev. Stat. Ann. § 30.927(2) (West 2009); Ariz. Rev. Stat. Ann. § 12-701(B) (2009); Utah Code Ann. § 78B-8-203 (West 2009).[6] Congress has given no indication that it would approve

[6] Although district courts in Arizona and Utah have concluded that Ariz. Rev. Stat. § 12-791(B) and Utah Code Ann. § 78B-8-203 are preempted by federal law, see Kobar ex rel. Kobar v. Novartis Corp., 378 F. Supp. 2d 1166, 1177 (D. Ariz. 2005); Grange v. Mylan Labs., Inc., No.

of opening the federal door to such a flood of state law based claims. See Sullivan II, 602 F. Supp. 2d at 537 ("Some cases might require courts to postulate whether the anticipated shift of case from state courts to the federal system is real or merely conjectural. This is not such a case."). Accordingly, the Court concludes that Plaintiffs' NJPLA claim does not meet either prong of the Grable analysis, and as a consequence, does not arise under federal law within the meaning of Section 1331.

IV. CONCLUSION

For the reasons expressed above, Plaintiffs' motions to remand will be granted.

Dated: 12-15-2009

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge

07-107, 2008 WL 4813311, at *7 (D. Utah 2008), the Supreme Court's recent decision in Wyeth v. Levine, -- U.S. --, 129 S.Ct. 1187 (2009) may call these decisions into question, see Sullivan II, 602 F. Supp. 2d at 534 n. 8.